Department of Labor and Industries

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PROVIDER BULLETIN

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THIS ISSUE

Payment for Opioids to Treat Chronic, Noncancer Pain

TO:

Advanced Registered Nurse Practitioners
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Purpose

This Provider Bulletin describes important changes that allow for the payment of opioids for the treatment of chronic, noncancer pain. These changes impact State Fund and Self-Insured claims and became effective January 20, 2000. Additionally, comprehensive treatment guidelines are included to assist providers in the clinical management of opioid trials and the outpatient prescription of oral opioids for injured workers with chronic, noncancer pain.

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D. New Rules (WACs): Pages 21-23. New rules (WACs) on opioids for chronic, noncancer pain.

Summary of policy changes

Until recently, the Washington Administrative Code (WACs) prohibited payment for opioids prescribed to injured workers for the treatment of chronic pain. Those rules were changed effective January 20, 2000. The department or self-insurer can now pay for opioids to treat chronic, noncancer pain as long as the worker:

- Has substantial reduction in pain *and* continuing substantial improvement in function, and
- Has not reached maximum medical improvement.

Summary of authorization and documentation requirements

In accordance with these new rules on the payment for opioids to treat chronic, noncancer pain, the treating physician is required to submit two new reports and a treatment agreement. These reports are needed for the department or self-insurer to authorize payment and to monitor your patient's progress. The *Opioid Progress Report Supplement* is required in addition to regular 60-day progress reports. Please review the table below to see, at a glance, more information about this required documentation. Copies of the *Opioid Progress Report Supplement* and *Functional Progress Form* can be found on pages 19 and 20.

When are reports needed?	Type of Report	Frequency of Report	Billing code	Paid amount	For details see:
When initiating treatment with opioids for chronic, noncancer pain	**Initial report** documenting the need for opioid treatment* (narrative)	All three of these reports are needed at the initiation of treatment for chronic, noncancer pain	1064M	$27.03	WAC 296-20-03020
	Opioid Progress Report Supplement - for baseline measurements of pain/function (department form) *F245-359-000*		1057M	$12.78	WAC 296-20-03021 WAC 296-20-03022 Attached form (page 19)
	Treatment agreement				WAC 296-20-03020 *Sample treatment agreement:* Pages 17-18 of this Provider Bulletin or on the Internet at www.lni.wa.gov/omd/opioids
With ongoing treatment	**Opioid Progress Report Supplement** (department form) *F245-359-000*	At least every 60 days	1057M	$12.78	WAC 296-20-03021 WAC 296-20-03022 Attached form (page 19)
	Functional Progress Form (department form) F245-363-000	Use of this form is voluntary but is encouraged after each visit to help track improvement			Attached form (page 20)
	Treatment agreement	Every six months			WAC 296-20-03020 *Sample treatment agreement:* Pages 17-18 of this Provider Bulletin or on the Internet at www.lni.wa.gov/omd/opioids

* No later than thirty days after the attending physician begins treating the worker with opioids for chronic, noncancer pain, the attending physician must submit a written report to the department or self-insurer in order for the department or self-insurer to pay for such treatment. See WAC 296-20-03020 for details.

What are the billing rules?

Physicians should bill the appropriate E&M codes for the evaluation and treatment of injured workers who may require opioids for the treatment of chronic, noncancer pain. Additionally, physicians may bill appropriate local codes, described in the next section, for preparation and submission of the initial documentation which establishes the necessity for treating the worker with opioids (See WAC 296-20-03020) and for the *Opioid Progress Report Supplement* (See WAC 296-20-03021).

What are the billing codes?

Use local code 1064M for the preparation and submission of the initial narrative report establishing the necessity of opioid treatment. This code pays $27.03.

Use local code 1057M for the preparation and submission of the *Opioid Progress Report Supplement.* This code pays $12.78.

Where can I obtain the new opioid forms?

All department forms can be obtained from the warehouse at:

Warehouse
Department of Labor & Industries
PO Box 44843
Olympia, WA 98504-4843

Use form # F245-359-000 to order the required *Opioid Progress Report Supplement.*
Use form # F245-363-000 to order the optional *Functional Progress Form*.

Both of these forms can also be found on the department's Internet home page via the "Forms" link at www.wa.gov/lni

Please note the following regarding coverage for prescriptions of injectable/parenteral opioids.

In general, prescriptions for injectable opioids are not covered. See WAC 296-20-03014 for exceptions. In addition, all other nonoral routes of administration of scheduled drugs that result in systemic availability of the drug equivalent to injectable routes will also not be covered.

For example: Use of the transdermal fentanyl system (Duragesic®) for chronic, noncancer pain will not be routinely covered. We have reviewed the literature and safety profile of this product. While the drug is absorbed relatively slowly, it reaches peak levels equivalent to intravenous use and is metabolized and excreted slowly. Therefore, because the pharmacokinetics of transdermal fentanyl demonstrates systemic availability that is equivalent to injectable routes, this product will not be routinely covered.

In addition, the FDA-approved product labeling states in part that Duragesic® is indicated in the management of chronic pain in patients who require continuous opioid analgesia for pain *that cannot be managed by lesser means.*

Therefore, on an exception basis only, the department will pay for the transdermal fentanyl system (Duragesic®) when the patient requires continuous opioid analgesia for pain that cannot be managed by lesser means AND, either

1. Other long-acting opioids cannot be tolerated, or
2. Medical contraindications preclude the use of oral opioids (e.g., the patient can't swallow pills, the patient has dementia and might not take the right amount of pills at the right time.)

Note: This does not apply to the use of opioids in the treatment of cancer pain. See WAC 296-20-03014.

GUIDELINES FOR OUTPATIENT PRESCRIPTION OF ORAL OPIOIDS FOR INJURED WORKERS WITH CHRONIC, NONCANCER PAIN

May 1, 2000

These guidelines were developed by the Washington State Department of Labor and Industries (L&I) in collaboration with the Washington State Medical Association (WSMA) Industrial Insurance and Rehabilitation Committee. These guidelines are intended to help doctors follow the 1998 *Guidelines for Management of Pain* issued by the Washington State Department of Health (DOH), and to apply the DOH guidelines to the care of injured workers with chronic, noncancer pain.

WHAT'S INSIDE

HELPFUL TOOLS

Are there tools to help me follow all relevant recommendations?

INTRODUCTION

Chronic, noncancer pain can be a complex and difficult management problem for both patient and physician. Chronic, noncancer pain may develop after an acute injury episode and is defined as pain that persists 2 - 4 months from the date of injury.

These guidelines are intended to help doctors to follow the 1998 *Guidelines for Management of Pain* issued by the Washington State Department of Health (DOH), and to apply the DOH guidelines to the care of injured workers with chronic, noncancer pain.

Long-term opioid use for chronic, noncancer pain is based on changing community standards and a body of evidence based on case reports of series of patients. There are few well-controlled or randomized controlled studies on the use of opioids in chronic pain states. There are no studies evaluating the effects of opioid use for chronic, noncancer pain exclusively in a worker's compensation population.

Even in the absence of strong research evidence, the community standard for the treatment of chronic, noncancer pain is changing. Findings from case reports do suggest that with appropriate patient selection and careful monitoring, opioid treatment can be effectively provided. Thus, a trial of opioid medications may be warranted.

These guidelines were developed by the Washington State Department of Labor and Industries (L&I) in collaboration with the Washington State Medical Association (WSMA) Industrial Insurance and Rehabilitation Committee. The guidelines are based on information from existing guidelines, extensive literature reviews, pharmacologic and medical references, interviews of experts and consultations with physicians in a wide variety of specialties. Careful, regularly documented compliance with these guidelines is necessary for the safety of injured workers, and to further the goal to return injured workers to health and to work.

Please note: The medical care a patient receives is a matter of choice for the patient to make in consultation with a treating physician. This principle is the same in cases with and without workers' compensation issues. Payment for medical care involves issues that may be distinct from treatment decisions. The Department of Labor and Industries pays for only that medical care which meets the requirements of the Washington Administrative Code and cannot pay for opioids once the patient reaches maximum medical improvement.

For which patients should I use these guidelines and why were the guidelines developed?
Please use these guidelines for all injured workers with chronic pain who are taking opioids.

These guidelines are intended to supplement the 1998 *Guidelines for Management of Pain* issued by the Washington State Department of Health (see Appendix 1, page 12). L&I endorses and encourages compliance with the DOH *Guidelines*. Since the *Guidelines for Management of Pain* were issued, problems of both under-treatment and over-treatment with controlled substances continue. L&I feels there is a need to make it easier for providers to follow the DOH *Guidelines* while treating injured workers, especially the sections on documentation.

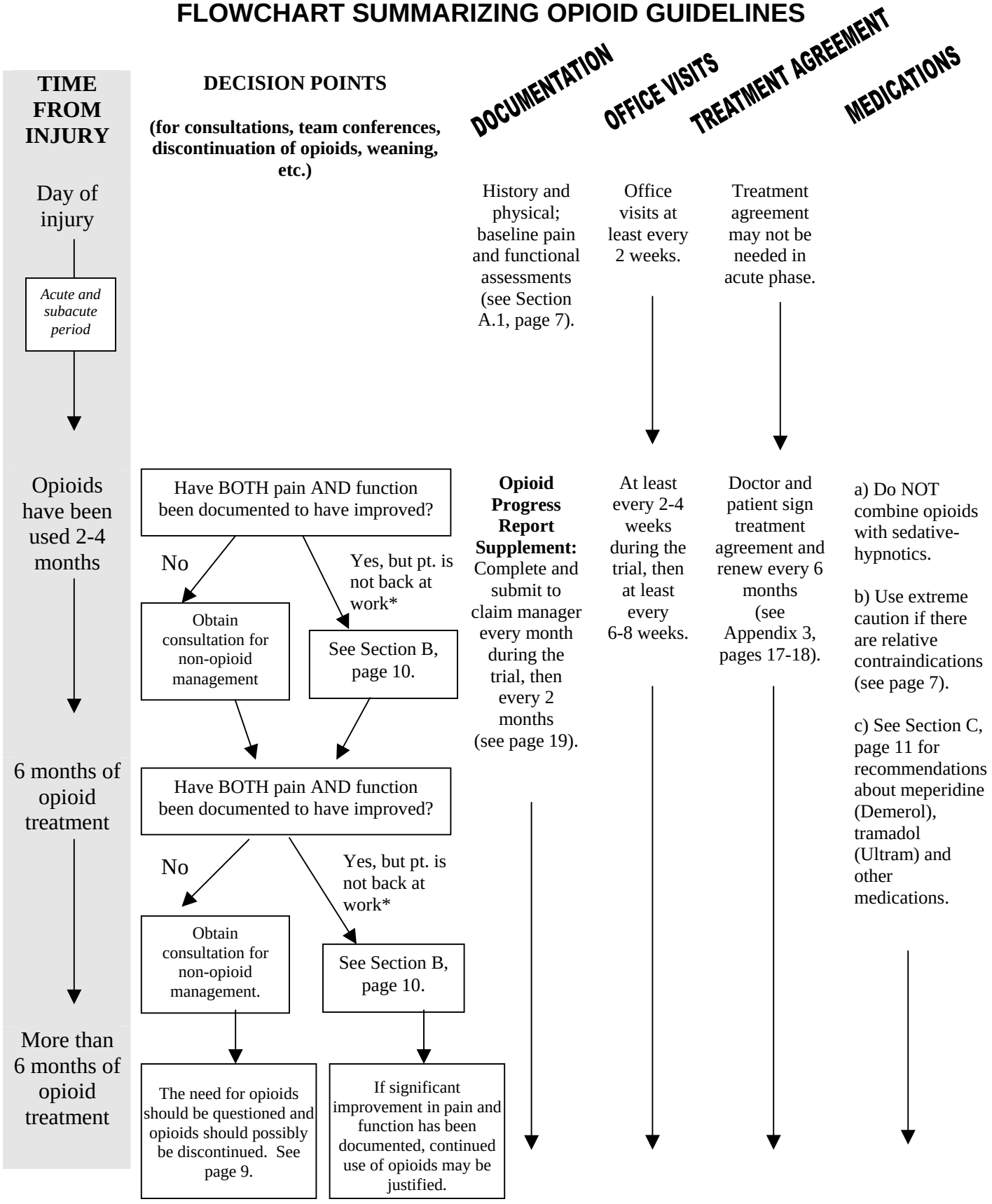
Also, L&I must consider factors such as whether care is curative or rehabilitative and whether a worker has reached a stable plateau from which further recovery is not expected (maximum medical improvement or MMI). *

In addition, operating heavy machinery, driving motor vehicles and other work activities may be dangerous to your patient and to his/her co-workers if controlled substances are being used. Your patient's livelihood may be affected for this reason.

Such considerations created a need to supplement the DOH *Guidelines for Management of Pain* for the worker population.

* *For details, please refer to L&I's Medical Aid Rules (WAC 296-20-03019 and WAC 296-20-03022).*

FLOWCHART SUMMARIZING OPIOID GUIDELINES



* *If pain and function have improved and patient has returned to work, please refer to Section F.8. "Assessment and Monitoring" of the DOH Guidelines on page 14.*

SECTION A. ASSESSMENT, MANAGEMENT AND DOCUMENTATION

1. How do I assess whether a formal trial of opioids for chronic pain is indicated?

You should address several questions to decide if a formal trial of opioids for chronic pain is indicated: 1) Are there reasonable alternatives other than opioids? 2) Is the patient likely to improve with opioids? and 3) Is the patient likely to abuse opioids or have other adverse outcomes? See Table 1 below for guidance on the latter two questions.

For guidance in the acute and subacute phases, refer to the "Guidelines for Outpatient Prescription of Controlled Substances for Workers on Time-Loss," developed in 1992 by L&I in collaboration with the Washington State Medical Association. These may be found in the *Attending Doctor's Handbook,* obtained by calling 1-800-848-0811.

Beyond 2-4 months of acute/subacute opioid use, the following assessment is strongly recommended:

a) Perform a baseline history and physical, including pain history and the impact of pain on the patient, a complete exam, review of previous diagnostic and therapeutic results and an assessment of co-existing conditions.
b) Obtain relevant baseline clinical or laboratory studies and/or urine drug screen, as indicated.
c) Based on the results of your assessment, identify the pain diagnosis. (See Table 1.)
d) Baseline pain and functional assessments should be documented. You may find it helpful to use a form like the attached *Opioid Progress Report Supplement* on page 19. ***Function includes social, physical, psychological, daily and work activities.***

(Continued on next page)

TABLE 1. HOW TO ASSESS WHETHER AN OPIOID TRIAL IS INDICATED

1) IS THE PATIENT LIKELY TO IMPROVE?

MAY IMPROVE	PROBABLY WILL NOT IMPROVE
1) Patient has taken opioids in the acute and subacute phases with some improvement in pain and function.	1) Patient has taken opioids in the acute and subacute phases with NO improvement in pain and function (assuming appropriate dosing, etc.).
2) Other conservative measures have failed (NSAIDs, etc.) and opioids have not been tried.	2) The pain diagnosis falls into the category of somatoform disorder. A consultation should be considered to address the underlying problem. In particular, conversion disorder, somatization disorder, or pain disorder associated with psychological factors (DSM-IV 307.80) is associated with poor response to opioids.
3) Your pain diagnosis falls into one of the following three categories: a) Nociceptive pain (for example, ischemia, tissue destruction, arthritis, cancer, arachnoiditis). b) Neuropathic pain (for example, sciatica, carpal tunnel syndrome, trigeminal neuralgia, post-herpetic neuralgia, phantom limb pain). c) Mixed nociceptive and neuropathic pain.	

2) IS THE PATIENT LIKELY TO ABUSE OPIOIDS OR HAVE OTHER ADVERSE OUTCOMES?

The risk of abuse or adverse outcome is high if any of the following are present:

1) History of alcohol or other substance abuse, or a history of chronic, high dose benzodiazepine use.
2) Active alcohol or other substance abuse.
3) Borderline personality disorders.
4) Mood disorders (e.g., depression) or psychotic disorders.
5) Other disorders that are primarily depressive in nature.
6) Off work for more than 6 months.
7) Poor response to opioids in the past.

Note: When special circumstances seem to warrant the use of these drugs in the types of patients noted above, referral for review is indicated.

e) Assess the worker's ability to participate in a return-to-work program, for example, work-hardening and vocational services.
f) Assess likelihood the patient can be weaned from opioids in the event there is no improvement in pain and function.
g) Decide whether you have the expertise to conduct a formal opioid trial for chronic pain. If not, make an appropriate referral.

Please note: In order for the Department of Labor & Industries or the self-insurer to pay for the opioid trial, the physician must submit a report no later than 30 days after beginning such treatment. (See WAC 296-20-03020 for details on the requirements of this report.)

2. How should I manage a formal trial of opioids for chronic pain?

The following general parameters should guide the attending physician's plan of care:

a) **Second opinion:** Consider a second opinion before planning the trial of opioids to assess whether a trial is indicated, and if so, how it should be conducted.

b) **Documentation:** ***You should use the one-page Opioid Progress Report Supplement, page 19.*** This will help you comply with all documentation requirements of the Department of Labor and Industries. (See WAC 296-20-03021 and 296-20-03022.)

Using the one-page Opioid Progress Report Supplement will also serve as a step-by-step guide to remind you and your patient to address a number of key issues, such as the treatment agreement, screening for addiction, return-to-work efforts, assessment of functional progress, consultations, medication history, treatment plan, etc.

c) **Contingency plan:** Plan ahead of time for both of these possibilities:
   1) The patient needs to be weaned from opioids because there has been no improvement in pain and function.
   2) Continuation of opioids beyond maximum medical improvement is indicated, and other forms of payment for the medications will be needed.

d) **Treatment agreement:** You and your patient should together sign a treatment agreement that outlines: the risks and benefits of opioid use, the conditions under which opioids will be prescribed, the physician's need to document overall improvement in function, and worker responsibilities (See Appendix 3, pages 17-18, Sample Opioid Treatment Agreement).

   Safety risks: Patients should especially be warned about potential side effects of opioids such as increased reaction time, clouded judgment, drowsiness and tolerance. Also, they should be warned about the possible danger associated with the use of opioids while operating heavy equipment or driving.

e) **Helping your patient return to work:** You should participate in a team conference with your patient, the employer (or potential new employers), the claim manager, the vocational counselor and others (preferably face-to-face) to explore return-to-work options. Which parties need to be involved will vary with each situation. Phone conferences often work well.

   For more information on resources available to you, see pages 9 – 14 of the Attending Doctor's Handbook (available at 1-800-848-0811).

f) **Principles for prescription of opioids:** You should follow these general principles:
   1) **Single prescribing physician:** There should be a single prescribing physician for all controlled substances.
   2) **Single pharmacy:** You should use a single pharmacy for prescription filling (whenever possible).
   3) **Lowest possible dose:** The lowest possible effective dose should be used to initiate therapy, and should be titrated, as needed to minimize both pain and medication side effects and maximize pain management and increased functioning.
   4) **Appearance of misuse of medications:** Be sure to watch out for and document any appearance of misuse of medications. Acquisition of drugs from other physicians, uncontrolled dose escalation or other aberrant behaviors must be carefully assessed. In all such patients, opioid use should be reconsidered and additional, more rigid guidelines applied if opioids continue. In some cases, tapering and discontinuation of opioid therapy will be necessary.

g) **Visit frequency:** Visits initially at least every 2 weeks for the first 2-4 months of the trial, then at least once every 6-8 weeks while receiving opioids.

h) **Consultations:** You should request a consultation if:

1) A dose in excess of 100-150 mg of oral morphine daily or its equivalent (for example, 45 mg of MS Contin every 8 hours) is being used;
2) Pain and functional status have not substantially improved after 3 months of opioid treatment;
3) A patient has a history of chemical dependency; or
4) A patient appears to have significant problems with depression, anxiety or irritability (a psychologic consultation may be indicated in these cases).

i) **Laboratory studies and drug screens:** Remember to order relevant ongoing clinical or laboratory studies (especially liver or kidney function screens), including drug screens, as indicated.

j) **Discontinuation vs. continuation of opioids:** After 6 months of a well-designed opioid trial, a physician should determine whether opioid therapy is appropriate for the patient, in accordance with the following:

1) If there has not been an overall improvement in function, opioids should usually be discontinued. (If there are extenuating circumstances that justify further use of opioids after 6 months of an opioid trial, these should be described in detail.)

2) If the patient has returned to work or has demonstrated substantial improvement both in function and reported pain level during a 6-month opioid trial, reasonable doses of opioids could continue. However, you and your patient should understand that state law forbids L&I from paying for opioids once the patient reaches maximum medical improvement. Please refer to L&I's *Medical Aid Rules* WAC 296-20-03019 through 296-20-03024 for further details. You should speak with your patient about other sources of payment for opioids when L&I can no longer pay. With this in mind, you should re-evaluate the need for opioids every two months, using techniques such as weaning and/or substitution of alternative treatments.

3) **Weaning time:** Weaning can be done safely by way of a slow taper. Patients who undergo intensive treatment programs in a pain center or a drug rehabilitation center can be tapered off opioids in 1-2 weeks. Patients being treated in an office-based practice should be tapered more slowly, but the taper should never take more than 3 months.

SECTION B. LONG-TERM ISSUES

1. What should I do if I have a patient who has *already* been on opioids for 6 months or more and is not back at work (or if I accept a *new* patient like this)?

If a patient has already received opioids for six months or more, you should do the following:

a) **Re-assess:** Perform a thorough re-assessment of the patient to see if anything has been missed.

1) Is the original diagnosis still present? Are there additional diagnoses that may contribute to the pain?

2) Has the patient been given other medications for management of pain? If so, how effective were they, what side effects were experienced and how severe were the side effects?

3) Has the patient tried other treatment methods or consulted with other specialists? If so, what alternative methods have been tried, length of alternative treatments, effectiveness, and/or specialist recommendations and effectiveness of those recommendations?

4) Has there been functional improvement since opioids were started? Try to quantify the improvement.

5) Would a psychological or psychiatric evaluation, completed by a psychiatrist or psychologist experienced in evaluating chronic pain patients, be helpful or necessary for you to determine effective pain management for this patient? Or has the patient completed a similar evaluation within the last 3-6 months? Psychosocial issues include motivation, attitude about pain/work, return-to-work options, home life, etc.

6) Has screening for elements of addiction been completed? Special caution should be exercised in patients with a history of substance abuse that cannot be attributed to a past mistaken diagnosis of addiction because this patient previously used opiates for pain management. Have you reviewed prior medical records, including L&I medical records and drug summaries? A drug summary may be obtained from the claim manager.

7) Review Sections A2, C1 and C2 for guidance on re-assessment and documentation. The essential material in these sections, particularly the treatment plan and its relationship to recovery, should be covered in your summary.

b) **Summarize:** Provide the insurer and others involved in the patient's care with a written summary of the case. Special attention should be given to the history of opioid use (how long, in what doses, etc.). Give a clear statement of your rationale if you think opioid treatment should continue.

c) **Help the patient return to work**: You should participate in a team conference with the patient, the employer (or potential new employers), the claim manager, the vocational counselor and others (preferably face-to-face) to explore return-to-work options. Which parties need to be involved will vary with each situation. Phone conferences sometimes work well.

For more information on resources available to you and how to bill for these services, see pages 9 – 14 of the Attending Doctor's Handbook (available at 1-800-848-0811).

d) **Triage:** If the patient has been treated with opioids for 6 months or more, you should ***automatically*** review the case as described in a) through d). At that point the physician should choose one of three pathways:

1) Modify the treatment plan to achieve optimum opioid benefit. Many patients like this will be taking combinations of medications that don't offer optimal pain control.

2) Discontinue opioid therapy.

3) Continue in opioid therapy.

In the third pathway, plans could be made to eventually move from the long-term opioid pathway up to one of the other pathways.

SECTION C. PRECAUTIONS IN PRESCRIBING

1. What precautions should I take when prescribing opioids?

a) ***DO NOT USE:***

Opioids in combination with sedative-hypnotics (such as benzodiazepines or barbiturates) for chronic, noncancer pain.

(There may be specific indications for such combinations, such as the co-existence of spasticity. In such cases, a consultation is strongly recommended.)

b) ***Use of these medications is NOT RECOMMENDED:***

1. Meperidine, which should not be prescribed for chronic pain.
2. Tramadol (Ultram) in combination with other opioids.
3. Carisoprodol (Soma).
4. Combination agonists and mixed agonists/antagonists. Mixed agonists/antagonists include such drugs as butorphanol (Stadol); dezocine (Dalgan), nalbuphine (Nubain) and pentazocine (Talwin).
5. Barbiturates (except if used to treat a seizure disorder).
6. Outpatient prescriptions of parenteral dosage forms of any drug.

c) ***Use caution when prescribing:***

1. Acetaminophen in doses greater than 4 grams (including, for example, combinations of drugs that include both an opioid and acetaminophen).
2. Cyclobenzaprine (Flexeril) in combination with tricyclic antidepressants (both share the same toxic potential).
3. Nonopioid drugs concomitantly with combination opioids (e.g., Tylenol given with Percocet).
4. Tramadol (Ultram) to patients at risk for seizures and/or who are also taking drugs which can precipitate seizures (e.g., SSRI antidepressants, tricyclic antidepressants).
5. Opioids, including tramadol, to patients with a prior or active history of chemical dependency.

d) Other recommendations include:

- Drug therapy should be individualized to the patient's specific pain condition and chosen on the basis of each drug's pharmacologic activity.
- Maintain patients on as few medications as possible. Drug interactions and adverse events increase as the number of medications in a regimen increases.
- Use adjuvant medications that are specific for a given pain condition.
- If possible, titrate only one drug at a time, while observing the patient for additive effects. Inappropriate medications should be tapered while initiating an appropriate pharmacologic regimen.

2. What signs may you see in a person with a prescription opioid problem?

The following guidelines were developed in a pain clinic setting. These guidelines may be a useful monitoring tool in managing chronic pain patients in your office setting. A patient may qualify as a prescription opiate abuser by meeting three or more of the criteria listed below. Physicians are encouraged to seek consultations (addictionologist, pain clinic, etc.) if 3 or more of these criteria are met. The patient:

a) Displays an overwhelming focus on opioid issues. For example, discussion of opioids occupies a significant portion of the visit and impedes progress with other issues regarding the patient's pain. This behavior persists beyond the third clinic session.
b) Has a pattern of early refills (3 or more) or escalating drug use in the absence of physician direction to do so.
c) Generates multiple telephone calls or visits to the office to request more opioids, early refills, or problems associated with the opioid prescription. A patient may qualify with fewer visits if he or she creates a disturbance with the office staff.
d) Demonstrates pattern of prescription problems for a variety of reasons that may include lost medications, spilled medications or stolen medications.
e) Has supplemental sources of opioids obtained from multiple providers, emergency rooms or illegal sources.
f) Has illicit drugs on urine screen.

APPENDIX 1

DEPARTMENT OF HEALTH
GUIDELINES FOR MANAGEMENT OF PAIN

Washington State Department of Health
Medical Quality Assurance Commission
Adopted 1998

A. Introduction

There are widespread concerns among patients throughout the state about access to appropriate medical treatment, including opioid therapy, for addressing chronic intractable pain. Similarly, providers express apprehensions about challenges by state disciplinary authorities when prescribing opioid analgesics for indicated medical treatment when serving the legitimate medical needs of pain patients. The undertreatment of chronic pain due to concerns about addiction and drug diversion affect the public health, safety, and welfare. There is a need for guidance which would: a) encourage appropriate treatment for pain management; b) reduce providers' fear of injudicious discipline; and c) protect the public from inappropriate prescribing practices and diversion.

B. Purpose statement

The Secretary of the Department of Health recommends the uniform adoption, by appropriate state regulatory authorities, of the following guidelines when managing pain. It is not the intent of these guidelines to define complete standards of acceptable medical care in the treatment of pain patients. These guidelines are not intended to direct clinical practice parameters. It is the intent that providers will have confidence that these guidelines are the standard by which opioid usage is evaluated.

C. Policy statement

Under generally accepted standards of medical practice, opioids may be prescribed for the treatment of acute or chronic pain including chronic pain associated with cancer and other noncancer pain conditions. Prescribing opioids requires special consideration. It is the position of the Department of Health that opioids may be prescribed, dispensed, or administered when there is an indicated medical need without fear of injudicious discipline.

D. Guidelines for opioid usage

1) Acute pain

Opioids are useful for patients with acute pain such as surgery, burn, or trauma. The goal of such treatment is to provide adequate and timely pain management to the patient. Side effects of opioids that are difficult to treat may occur and must be balanced against the benefits of pain relief. The provider should, for any patient who has a history of alcoholism or other drug addictions, carefully monitor medications and when available seek appropriate consultation.

2) Chronic Pain Associated with Cancer

Chronic pain associated with cancer may often be successfully managed with opioids. If use of opioids is the primary analgesic strategy, adequate doses should be given frequently enough to keep the patient continuously comfortable. Addiction is rare in patients with cancer pain; tolerance and physical dependency are often unavoidable and should not interfere with opioid prescribing. Not all pain in patients with cancer is responsive to opioids; alternative strategies for managing the pain should also be made available.

3) Other Chronic Pain Conditions

Opioid analgesics can be useful in the treatment of patients with intractable noncancer pain especially, where efforts to remove the cause of pain or to treat it with other modalities have failed or were not fully successful. The pain of such patients may have a number of different etiologies and may require several modalities. In addition, the extent to which pain is associated with psychological, physical, and social impairment varies greatly. Therefore, the selection for a trial of opioid therapy should be based on a careful assessment of the pain as well as the impairment experienced by the patient. Continuation of opioid therapy should be based on the provider's evaluation of the results of treatment, including the degree of pain relief, changes in psychological, physical, and social functioning, and appropriate utilization of health services. Providers

are encouraged to obtain consultation from providers who are knowledgeable in pain management, particularly when managing patients with a history of alcohol abuse or previous chronic opioid use.

E. Definitions

1. **Addiction** – A disease process involving use of psychoactive substances wherein there is loss of control, compulsive use, and continued use despite adverse social, physical, psychological, or spiritual consequences.
2. **Physical dependence** – A physiologic state of adaptation to a specific psychoactive substance characterized by the emergence of a withdrawal syndrome during abstinence, which may be relieved in total or in part by re-administration of the substance. Physical dependence is not necessarily associated with full blown addiction, and condition does not always equate with addiction.
3. **Psychological dependence** – A subjective sense of need for a specific substance, either for its positive effects or to avoid negative effects associated with its abstinence.
4. **Tolerance** – State in which an increased dosage of a psychoactive substance is needed to produce a desired effect.
5. **Withdrawal syndrome** – The onset of a predictable constellation of signs and symptoms following the abrupt discontinuation of, or rapid decrease in, dosage of a psychoactive substance.
6. **Acute pain** – An essential biologic signal of the potential for or the extent of injury. It is usually short-lived and is associated with hyperactivity of the sympathetic nervous system; e.g. tachycardia, increased respiratory rate and blood pressure, diaphoresis, and papillary dilation. The concurrent affect is anxiety.
7. **Chronic pain** – Pain persistent beyond expected healing time and often cannot be ascribed to a specific injury. Chronic pain may not have a well-defined onset and by definition does not respond to treatment directed at its causes.
8. **Intractable pain in a noncancer patient** – Pain in which the cause cannot be removed or otherwise treated and no relief or cure has been found after reasonable efforts.

F. Guidelines for assessment and documentation in noncancer pain

Alternative strategies for managing pain must be explored. If alternative strategies for managing the pain are unsuccessful, long term opioid therapy can be added. The goal is not merely to treat the symptoms of pain, but to devise pain management strategies which deal effectively with all aspects of the patient's pain syndrome, including psychological, physical, social, and work-related factors. Documentation in the patient's medical record should include:

1. **History and medical examination** – A complete physical examination and comprehensive medical history should be part of the active treatment record including, but not limited to, a review of past pain treatment outcomes and any history of addiction risks to establish a diagnosis and treatment plan.
2. **Diagnosis and medical indication** – A working diagnosis must be delineated, which includes the presence of a recognized medical indication for the use of any treatment or medication.
3. **Written treatment plan with recorded measurable objectives** – The plan should have clearly stated, measurable objectives, indication of further planned diagnostic evaluation, and alternative treatments.
4. **Informed consent** – Discussions of risks and benefits should be noted in some format in the patient's record.
5. **Periodic reviews and modifications indicated** – At these periodic reviews, the provider should reassess the treatment plan, the patient's clinical course, and outcome goals with particular attention paid to disease progression, side effect and emergence of new conditions.
6. **Consultation** – The treating provider should be knowledgeable and competent in referring patients to the appropriate specialist if needed and noting in the patient's record the treating provider's interpretation of the consultation reports. Additionally, a new patient with evidence of at-risk patterns of opioid usage should be evaluated by a knowledgeable specialist.
7. **Records** – The provider should keep accurate and complete records documenting the dates and clinical findings for all evaluations, consultations, treatments, medications and patient instructions.

8. **Assessment and monitoring** – Some patients with chronic pain not associated with cancer may be at risk of developing increasing opioid consumption without objective improvement in functional status. Subjective reports by the patient should be supported by objective observations. Objective measures in the patient's condition are determined by an ongoing assessment of the patient's functional status, including the ability to engage in work or other gainful activities, patient consumption of health care resources, positive answers to specific questions about the pain intensity and its interference with activities of daily living, quality of family life and social activities, and physical activity of the patient as observed by the physician.

   Physical dependence and tolerance are normal physiologic consequences of extended opioid therapy and are not the same as addiction. Addiction is a disease with behavior characterized by psychological dependence and aberrant drug related behaviors. Addicts compulsively use drugs for non-medical purposes despite harmful effects; a person who is addicted may also be physically dependent or tolerant. Patients with chronic pain should not be considered addicts merely because they are being treated with opioids.

The physician is responsible for monitoring the dosage of the opioid. Monitoring includes ongoing assessment of patient compliance with drug prescriptions and related treatment plans. Communication between health care providers is essential. The patient should receive long term analgesic medications from one physician and where possible one pharmacy. All providers should be particularly cautious with patients with a history of alcoholism or other drug addiction when prescribing long term opioids. Consults with addiction specialists are recommended.

G. Patient Responsibilities

1. It is the patient's responsibility to candidly provide the treatment provider with a complete and accurate treatment history, including past medical records, past pain treatment and alcohol and other drug addiction history.
2. The patient should participate as fully as possible in all treatment decisions.
3. The patient and family members, if available, should inform the prescriber of all drug side effects and concerns regarding prescription drugs.
4. The patient should not use other psychoactive agents, including alcohol, naturopathic products or over-the-counter drugs without agreement to the prescriber.
5. The patient should use the same name when receiving medical care to assure completeness of the medical record.
6. The patient should demand respect and expect to be believed.
7. The patient should keep an open mind and be willing to work with the treatment provider, including:
   a. negotiate with the provider to arrive at an acceptable plan of treatment;
   b. be open in trying alternative treatment strategies; and
   c. follow the treatment provider's instructions precisely.
8. The patient should, where possible, get all central nervous system medications from one provider. If this is not possible, the patient should inform each provider of all medications he/she is receiving.
9. The patient should, where possible, have all prescriptions filled at a single pharmacy.
10. The patient should not horde, share, or sell medications.
11. The patient should be aware that providers may, by law, share information with other providers about the patient's care.

APPENDIX 2

HOW WERE THESE GUIDELINES DEVELOPED?

These guidelines were developed by the Washington State Department of Labor and Industries (L&I) in collaboration with the Washington State Medical Association (WSMA) Industrial Insurance and Rehabilitation Committee. The WSMA is charged by the Washington Administrative Code with the responsibility and authority to advise L&I on issues relating to medical care of injured workers.

Beginning in 1998 numerous meetings of the Treatment Guidelines Subcommittee were devoted to discussion of medical, legal, adjudicative and other aspects of chronic pain management. The subcommittee consisted of physicians representing a variety of specialties, including anesthesiology, internal medicine, neurology, occupational medicine, orthopedic surgery, physical medicine and rehabilitation, and plastic surgery, among others. The subcommittee included one doctor who had participated in the creation of the Department of Health "Guidelines for Management of Pain."

The subcommittee carefully reviewed the medical literature on the topic of opioids and their use for chronic noncancer pain. The subcommittee refined a series of drafts, then used a consensus process to arrive at a draft for wider distribution and comment.

The subcommittee solicited and received comments from dozens of authorities from many parts of the United States. The authorities represented a spectrum of disciplines, specialties and perspectives, including non-physicians such as representatives of patient advocacy organizations.

After further discussion and incorporation of changes based on stakeholder input, the subcommittee presented a final draft to the WSMA and recommended that the WSMA approve the guidelines. The WSMA approved the guidelines in April 1999. Additional comments were received, and the WSMA approved a number of enhancements to the guidelines. These guidelines are intended to be reviewed and amended on a regular basis depending on emerging scientific data and on changing community standards.

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APPENDIX 3

SAMPLE OPIOID TREATMENT AGREEMENT

Patient Name:_____ ***Date:***_____

Opioid (narcotic) treatment for chronic pain is used to reduce pain and improve what you are able to do each day. Along with opioid treatment, other medical care may be prescribed to help improve your ability to do daily activities. This may include exercise, use of non-narcotic analgesics, physical therapy, psychological counseling or other therapies or treatment. Vocational counseling may be provided to assist in your return to work effort.

To the doctor: Keep signed originals in your file; give a photocopy to the patient. Renew at least every 6 months.

I, _____, understand that compliance with the following guidelines is important in continuing pain treatment with Dr. _____.

1. I understand that I have the following responsibilities:
   a. I will take medications only at the dose and frequency prescribed.
   b. I will not increase or change medications without the approval of this doctor.
   c. I will actively participate in RTW efforts and in any program designed to improve function (including social, physical, psychological and daily or work activities).
   d. I will not request opioids or any other pain medicine from physicians other than from this doctor. This doctor will approve or prescribe all other mind and mood altering drugs.
   e. I will inform this doctor of all other medications that I am taking.
   f. I will obtain all medications from one pharmacy, when possible known to this doctor with full consent to talk with the pharmacist given by signing this agreement.
   g. I will protect my prescriptions and medications. Only one lost prescription or medication will be replaced in a single calendar year. I will keep all medications from children.
   h. I agree to participate in psychiatric or psychological assessments, if necessary.
   i. If I have an addiction problem, I will not use illegal or street drugs or alcohol. This doctor may ask me to follow through with a program to address this issue. Such programs may include the following:
      - 12-step program and securing a sponsor
      - Individual counseling
      - Inpatient or outpatient treatment
      - Other: _____

2. I understand that in the event of an emergency, this doctor should be contacted and the problem will be discussed with the emergency room or other treating physician. I am responsible for signing a consent to request record transfer to this doctor. No more than 3 days of medications may be prescribed by the emergency room or other physician without this doctor's approval.

3. I understand that I will consent to random drug screening. A drug screen is a laboratory test in which a sample of my urine or blood is checked to see what drugs I have been taking.

4. I will keep my scheduled appointments and/or cancel my appointment a minimum of 24 hours prior to the appointment.

5. I understand that this doctor may stop prescribing opioids or change the treatment plan if:
   a. I do not show any improvement in pain from opioids or my physical activity has not improved.
   b. My behavior is inconsistent with the responsibilities outlined in #1 above.
   c. I give, sell or misuse the opioid medications.
   d. I develop rapid tolerance or loss of improvement from the treatment.
   e. I obtain opioids from other than this doctor.
   f. I refuse to cooperate when asked to get a drug screen.
   g. If an addiction problem is identified as a result of prescribed treatment or any other addictive substance.
   h. If I am unable to keep follow-up appointments.

_____ _____

Patient Signature ***Date*** ***Physician Signature*** ***Date***

(First of two pages - continued on next page…)

SAMPLE OPIOID TREATMENT AGREEMENT (*continued*)

YOUR SAFETY RISKS WHILE WORKING UNDER THE INFLUENCE OF OPIOIDS:

You should be aware of potential side effects of opioids such as decreased reaction time, clouded judgment, drowsiness and tolerance. Also, you should know about the possible danger associated with the use of opioids while operating heavy equipment or driving.

SIDE EFFECTS OF OPIOIDS:

- Confusion or other change in thinking abilities
- Nausea
- Constipation
- Vomiting
- Problems with coordination or balance that may make it unsafe to operate dangerous equipment or motor vehicles
- Sleepiness or drowsiness
- Breathing too slowly – overdose can stop your breathing and lead to death
- Aggravation of depression
- Dry mouth

THESE SIDE EFFECTS MAY BE MADE WORSE IF YOU MIX OPIOIDS WITH OTHER DRUGS, INCLUDING ALCOHOL.

RISKS:

- Physical dependence. This means that abrupt stopping of the drug may lead to withdrawal symptoms characterized by one or more of the following:

Runny nose	Difficulty sleeping for several days
Diarrhea	Abdominal cramping
Sweating	'Goose bumps'
Rapid heart rate	Nervousness

- Psychological dependence. This means it is possible that stopping the drug will cause you to miss or crave it.
- Tolerance. This means you may need more and more drug to get the same effect.
- Addiction. A small percentage of patients may develop addiction problems based on genetic or other factors.
- Problems with pregnancy. If you are pregnant or contemplating pregnancy, discuss with your physician.

PAYMENT OF MEDICATIONS:

State law forbids L&I from paying for opioids once the patient reaches maximum medical improvement. You and your doctor should discuss other sources of payment for opioids when L&I can no longer pay.

RECOMMENDATIONS TO MANAGE YOUR MEDICATIONS:

- Keep a diary of the pain medications you are taking, the medication dose, time of day you are taking them, their effectiveness and any side effects you may be having.
- Use of a medication box that you can purchase at your pharmacy that is already divided in to the days of the week and times of the day so it is easier to remember when to take your medications.
- Take along only the amount of medicine you need when leaving home so there is less risk of losing all your medications at the same time.

I have read this document, understand and have had all my questions answered satisfactorily. I consent to the use of opioids to help control my pain and I understand that my treatment with opioids will be carried out as described above.

_____ _____

Patient Signature ***Date*** ***Physician Signature*** ***Date***

This is where the OPIOID PROGRESS REPORT SUPPLEMENT form goes. Appendix? Page #?

Page 1 of 1

This is where the FUNCTIONAL PROGRESS FORM goes. Appendix? Just a page number?

Changes to the Washington Administrative Code (WAC)

Until recently, the Washington Administrative Code (WACs) prohibited payment for opioids prescribed to injured workers for the treatment of chronic pain. Those rules were changed effective January 20, 2000. The revised WACs pertaining to opioids are presented below. (Please see Provider Bulletin 00-01 for a complete listing of the new drug and medication rules.)

WAC 296-20-03014 Which drugs have specific limitations?

(1) **Injectables**. Prescriptions for injectable opioids or other analgesics, sedatives, antihistamines, tranquilizers, psychotropics, vitamins, minerals, food supplements, and hormones are not covered. Exceptions: The department or self-insurer covers injectable medications under the following circumstances.

(a) Indicated injectable drugs for the following:

- Inpatients; or
- During emergency treatment of a life-threatening condition/injury; or
- During outpatient treatment of severe soft tissue injuries, burns or fractures when needed for dressing or cast changes; or
- During the perioperative period and the postoperative period, not to exceed forty-eight hours from the time of discharge.

(b) Prescriptions of injectable insulin, heparin, anti-migraine medications, or impotency treatment, when proper and necessary.

(2) **Noninjectable scheduled drugs administered by other than the oral route**. Nonoral routes of administration of scheduled drugs that result in systemic availability of the drug equivalent to injectable routes will also not be covered.

(3) **Sedative-hypnotics**. During the chronic stage of an industrial injury or occupational disease, payment for scheduled sedatives and hypnotics will not be authorized.

(4) **Benzodiazepines**. Payment for prescriptions for benzodiazepines are limited to the following types of patients:

- Hospitalized patients;
- Claimants with an accepted psychiatric disorder for which benzodiazepines are indicated;
- Claimants with an unrelated psychiatric disorder that is retarding recovery but which the department or self-insurer has temporarily authorized treatment (see WAC 296-20-055) and for which benzodiazepines are indicated; and
- Other outpatients for not more than thirty days for the life of the claim.

(5) **Cancer**. When cancer or any other end-stage disease is an accepted condition, the department or self-insurer may authorize payment for any indicated scheduled drug and by any indicated route of administration.

(6) **Spinal cord injuries**. When a spinal cord injury is an accepted condition, the department or self-insurer may authorize payment for anti-spasticity medications by any indicated route of administration (e.g., some benzodiazepines, Baclofen). Prior authorization is required.

Note: See the department formulary for specific limitations and prior authorization requirements of other drugs.

WAC 296-20-03019 Under what conditions will the department or self-insurer pay for oral opioid treatment for chronic, noncancer pain?

Chronic, noncancer pain may develop after an acute injury episode. It is defined as pain that typically persists beyond two to four months following the injury.

The department or self-insurer may pay for oral opioids for the treatment of chronic, noncancer pain caused by an accepted condition when that treatment is proper and necessary. See WAC 296-20-01002 for the definition of "proper and necessary" health care services.

WAC 296-20-03020 What are the authorization requirements for treatment of chronic, noncancer pain with opioids?

No later than thirty days after the attending physician begins treating the worker with opioids for chronic, noncancer pain, the attending physician must submit a written report to the department or self-insurer in order for the department or self-insurer to pay for such treatment. The written report must include the following:

- A treatment plan with time-limited goals;
- A consideration of relevant prior medical history;
- A summary of conservative care rendered to the worker that focused on reactivation and return to work;
- A statement on why prior or alternative conservative measures may have failed or are not appropriate as sole treatment;
- A summary of any consultations that have been obtained, particularly those that have addressed factors that may be barriers to recovery;
- A statement that the attending physician has conducted appropriate screening for factors that may significantly increase the risk of abuse or adverse outcomes (e.g., a history of alcohol or other substance abuse); and
- An opioid treatment agreement that has been signed by the worker and the attending physician. This agreement must be renewed every six months. The treatment agreement must outline the risks and benefits of opioid use, the conditions under which opioids will be prescribed, the physician's need to document overall improvement in pain and function, and the worker's responsibilities.

WAC 296-20-03021 What documentation is required to be submitted for continued coverage of opioids to treat chronic, noncancer pain?

In addition to the general documentation required by the department or self-insurer, the attending physician must submit the following information at least every sixty days when treating with opioids:

- Documentation of drug screenings, consultations, and all other treatment trials;
- Documentation of outcomes and responses, including pain intensity and functional levels; and
- Any modifications to the treatment plan.

The physician must use a form developed by the department, or a substantially equivalent form, to document the patient's improvement in pain intensity and functional levels. This form may be included as part of a sixty-day report.

WAC 296-20-03022 How long will the department or self-insurer continue to pay for opioids to treat chronic, noncancer pain?

The department or self-insurer will continue to pay for treatment with opioids so long as the physician documents:

- Substantial reduction of the patient's pain intensity; and
- Continuing substantial improvement in the patient's function.

Once the worker's condition has reached maximum medical improvement, further treatment with opioids is not payable. Opioid treatment for chronic, noncancer pain past the first three months of such treatment without documentation of substantial improvement is presumed to be not proper and necessary.

WAC 296-20-03023 When may the department or self-insurer deny payment of opioid medications used to treat chronic, noncancer pain?

Payment for opioid medications may be denied in any of the following circumstances:

- Absent or inadequate documentation;
- Noncompliance with the treatment plan;
- Pain and functional status have not substantially improved after three months of opioid treatment; or
- Evidence of misuse or abuse of the opioid medication or other drugs, or noncompliance with the attending physician's request for a drug screen.

WAC 296-20-03024 Will the department or self-insurer pay for nonopioid medications for the treatment of chronic, noncancer pain?

The department or self-insurer may pay for nonopioid medication for the treatment of chronic, noncancer pain when it is proper and necessary.

For example, some drugs such as anti-convulsants, anti-depressants, and others have been demonstrated to be useful in the treatment of chronic pain and may be approved when proper and necessary.